

# **Oncologic Drugs Advisory Committee**

**September 2, 2009**

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Hilton Washington DC/Silver Spring, Silver Spring, Maryland

## **ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)**

S. Gail Eckhardt, M.D. (Chair)

Professor and Division Head, Medical Oncology  
University of Colorado at Denver  
12801 E. 17th Avenue  
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Ralph Freedman, M.D., Ph.D.

Clinical Professor  
Department of Gynecologic Oncology  
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Michael Link, M.D.

The Lydia J. Lee Professor of Pediatrics  
Chief, Division of Hematology/Oncology  
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Gary Lyman, M.D., M.P.H.

Director, Health Services and Outcomes  
Research Program- Oncology  
Duke University Medical Center  
Box 3645  
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Virginia Mason, R.N. (Consumer Representative)

Executive Director  
Inflammatory Breast Cancer Research Foundation  
P.O. Box 786  
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Ronald Richardson, M.D.

Consultant, Department of Medical Oncology  
Mayo Clinic  
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Mikael Sekeres, M.D., M.S.

Associate Professor of Medicine  
Staff  
Cleveland Clinic Taussig Cancer Institute  
Department of Hematologic Oncology and  
Blood Disorders  
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Margaret Tempero, M.D.

Deputy Director, UCSF Helen Diller Family  
Comprehensive Cancer Center  
University of California, San Francisco  
UCSF Cancer Center  
1600 Divisadero Street, Room B726  
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San Francisco, CA 94115

Wyndham Wilson, M.D. (PM Session Only)

Chief, Lymphoma Therapeutics Section  
Metabolism Branch  
Center for Cancer Research  
National Cancer Institute  
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Rockville, MD 20892

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## **INDUSTRY REPRESENTATIVE (Non-Voting)**

Gregory Curt, M.D.

U.S. Medical Science Lead, Emerging Products  
AstraZeneca Oncology  
P.O. Box 223  
Garrett Park, MD 20896

## **TEMPORARY VOTING MEMBERS (Morning Session)**

Thomas Fleming, Ph.D.

Professor  
Department of Biostatistics  
University of Washington, Seattle  
Box 357232  
Seattle, WA 98195

Richard Little, M.D.

Senior Investigator  
Head, Hematologic & AIDS-related  
Malignancies  
and Hematopoietic Stem Cell Transplantation  
Clinical Investigations Branch  
National Cancer Institute  
CTEP/DCTD/NCI  
6130 Executive Blvd. Suite 7025  
Executive Plaza North  
Rockville, MD 20852

Karl Schwartz (Patient Representative)

Riegelsville, PA 18077

## **GUEST SPEAKER (Non-Voting)**

Mira Pavlovic, M.D. (Guest Speaker)

Scientific Advice Working Party Vice-Chair  
and Efficacy Working Party member (EMA)  
Head of Scientific Advice at  
French Medicines Agency (AFSSAPS), 143-147,  
Boulevard Anatole France  
93285 Saint-Denis Cedex, France

## **TEMPORARY VOTING MEMBERS (Afternoon Session)**

Catherine Broome, M.D.

Department of Medicine  
Division of Hematology/Oncology  
Georgetown University  
Lombardi Comprehensive Cancer  
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Brad Kahl, M.D.

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Professor of Medicine  
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Chief, Hematology Section  
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Karl Schwartz (Patient Representative)

Riegelsville, PA 18077

Jane Winter, M.D.

Professor of Medicine  
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Northwestern University  
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## FDA Non-Voting

### Morning Session

Richard Pazdur, M.D.

Director  
Office of Oncology Drug Products (OODP),  
OND, CDER, FDA

Robert Justice, M.D.

Director  
Division of Drug Oncology Products (DDOP),  
OODP, OND, CDER, FDA

V. Ellen Maher, M.D.

Medical Team Leader  
DDOP, OODP, OND, CDER, FDA

Qin Ryan, M.D.

Medical Officer  
DDOP, OODP, OND, CDER, FDA

### Afternoon Session

Richard Pazdur, M.D.

Director  
Office of Oncology Drug Products (OODP),  
OND, CDER, FDA

Robert Justice, M.D.

Director  
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Shakun Malik, M.D.

Medical Officer  
DDOP, OODP, OND, CDER, FDA

Qiang (Casey) Xu, Ph.D.

Statistical Reviewer - Drug Oncology  
Division of Biostatistics 5 (DB5),  
Office of Biostatistics (OB),  
Office of Translational Science (OTS),  
CDER, FDA

Ke Liu, MD, Ph.D.

Medical Team Leader  
DDOP, OODP, OND, CDER, FDA